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# Factors affecting patency of in situ saphenous vein bypass: 2-year results from LIMBSAVE (Treatment of critical Limb IscheMia with infragenicular Bypass adopting in situ SAphenous VEin technique) registry

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**ORIGINAL ARTICLE**

**BRIEF TITLE:** 2-year outcomes of LIMBSAVE registry

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**ABSTRACT**

OBJECTIVES:

Aim is to demonstrate contemporary outcomes of in situ saphenous vein bypass with the use of a valvulotome.

DESIGN:

Analysis of two-year outcomes of a multicenter registry based on the treatment of critical Limb IscheMia with infragenicular Bypass adopting in situ SAphenous VEin technique (LIMBSAVE).

MATERIALS:

Between January 2018 and December 2019 541 patients in 43 centers have been enrolled. In all patients an innovative valvulotome was used.

METHODS:

Early outcomes were assessed. Two-year outcomes according to Kaplan-Meier curves in terms of patencies, and limb salvage were evaluated. Associations of patient and procedure variables were analysed with univariate and multivariate analyses.

RESULTS:

In all cases valvulotome was able to lyse the valves. Vein injuries due to the in situ technique was 3.5%. Thirty-day mortality and major amputation rates were 3% and 0.9%, respectively. Mean follow-up was 12.1 months. Two-year estimated primary patency, primary assisted patency, secondary patency, and limb salvage were 69.1%, 81.4%, 86.5%, and 94.5%, respectively. Multivariate analysis showed association of preoperative vein diameter < 3 mm with lower primary patency (HR 14.3, $p < .001$), primary assisted patency (HR 9.4, $p = .002$), secondary patency (HR 7.2, $p = .007$), and limb salvage (HR 7.8, $p = .005$) rates. Distal anastomosis on a tibial/foot vessel also had association with lower primary patency (HR 4.8, $p = .033$), and primary assisted patency (HR 6, $p = .011$) rates. Use of a suprafascial tributary

collateral as a graft confirmed association with lower primary patency (HR 6.7, $p$ = .013), and primary assisted patency (HR 4.2, $p$ = .042) rates.

CONCLUSIONS:

Vein diameter < 3 mm, distal anastomosis on a tibial/foot vessel, and use of a suprafascial tributary collateral as a graft were significantly associated with loss of patency and limb loss during follow-up.

**Keywords**: critical limb-threatening ischemia, limb salvage, in situ saphenous vein, peripheral bypass.

**WHAT THIS PAPER ADDS**

This paper reports the outcomes of the in situ saphenous bypass technique obtained with a new valvulotome designed to be used in smaller veins. This multicenter experience demonstrated the safety and feasibility of this device (HYDRO LeMaitre® Valvulotome; LeMaitre Vascular, Burlington, MA, USA). However, vein diameter < 3 mm remains a significant predictive factor of bypass failure and limb loss. In addition, distal anastomosis on a tibial/foot artery, and use of a suprafascial tributary collateral as a graft represent factors associated with a higher rate of graft failure.

## INTRODUCTION

Open surgical bypass for long infrainguinal arterial occlusions is the preferred first approach in patients with a life expectancy of more than two years[1-2]. The use of autologous vein is the conduit of choice for infrainguinal bypass[3], with the saphenous vein graft historically considered as the gold standard[4].

In situ saphenous vein bypass is an old and well-established technique for the treatment of patients with infrainguinal arterial occlusive disease[5]. In the 1990's, substantial single-center experience demonstrated the long-term effectiveness of this technique in terms of secondary patency and limb salvage rates[6].

Various published papers report on comparative analyses between the in situ and reversed saphenous vein bypass techniques with comparable outcomes in most of these studies[7-13].

In the current endovascular era, however, there is limited data available on the in situ saphenous bypass. There is a lack of multicenter experiences reporting on the use of the in situ technique to treat patients with long infrainguinal occlusions and chronic limb-threatening ischemia (CLTI).

The aim of this study was to evaluate the 2-year outcomes of a national, multicenter, observational, prospective registry of patients with CLTI receiving an infragenicular bypass with an in situ saphenous vein technique, using a valvulotome.

## MATERIALS ANS METHODS

### Study population

Between January 2018 and December 2019 541 patients treated in 43 Italian departments of Vascular Surgery were included in the LIMBSAVE registry (*critical Limb IscheMia with infragenicular Bypass adopting in situ SAphenous VEin technique*). In all patients a hydrophilic, self-centering, self-calibrating valvulotome (HYDRO LeMaitre®, LeMaitre

Vascular, Burlington, MA, USA) was used to obtain a pulsatile saphenous vein as an infragenicular bypass.

The registry has been designed on the concept of "real world". Therefore, all patients were treated based on hospitals protocols in terms of pre- and intraoperative diagnostic evaluation. Furthermore, no strict indications have been established in terms of postoperative medical therapy. The protocol of the registry has been published[15]

**HYDRO LeMaitre® valvulotome procedure**

All saphenous veins were prepared with the HYDRO LeMaitre® valvulotome. The valvulotome features a hydrophilic coating of the outer catheter which ensures less traumatic insertion and easier advancement through the vein. The valvulotome includes a blade range from 1.5 to 6 mm and has self-sizing and self-centering hoops/blades. The depth markers are placed every 10 cm which ensures easy valve and tributary localization and aid for more controlled positioning in the vein. In addition, the green safety stripes near the cutting blades enable a more controlled ablation of the last distal valve.

After performing the proximal anastomosis, the valvulotome is retrogradely inserted into the vein and pushed up to the proximal anastomosis under visual inspection. To lyse the vein valves, the hoops/blades are opened and the system is slowly pulled back from the proximal anastomosis. Full details on the HYDRO valvulotome procedure were previously reported[14].

**Inclusion/exclusion criteria**

Inclusion criteria were:

1. Patients with CLTI in presence of rest pain and/or ischaemic lesions (Rutherford categories 4-5-6);

2. Availability of ipsilateral autologous saphenous vein in the limb to be operated on with a minimum diameter of not less than 1.6 mm;
3. Distal anastomosis located at the level of the infragenicular popliteal artery, tibioperoneal trunk, one of the 3 tibial vessels (anterior tibial artery, posterior tibial artery, peroneal artery) or one of the foot arteries;
4. Age over 18 years;
5. Signed informed consent form.

Exclusion criterion was:

1. Patients with aneurysmal disease of the lower limbs.

CLTI was defined as a clinical presentation of peripheral artery disease (PAD) in combination with rest pain, gangrene, or a lower limb ulceration of >2 weeks duration, and one or more abnormal hemodynamic parameters, such as ankle-brachial index or toe pressure[2].

**Patient data and follow-up schedule**

Clinical examinations and Duplex scans were performed at the following study time-points: enrollment, day of the procedure, and post-procedure at 30 days, 3 months, 6 months, 9 months, 12 months, 18 months, and 24 months.

A computed tomography angiography (CTA) or a digital subtraction angiography (DSA) was only performed on surgeon's or center's discretion.

The diameter of the great saphenous vein was evaluated on preoperative Duplex scan. Evaluated regions were the proximal part of the thigh, distal part of the thigh, proximal part of the leg, and distal part of the leg.

Ideally, the Duplex scans for vein mapping were performed while patients were in standing position however this was often not possible in patients with CLTI. In these cases, the Duplex scans were performed in the supine reverse Trendelenburg position (+ 15°).

An accurate preoperative mapping of the great saphenous vein was performed on the day before the procedure and then checked perioperatively before surgical incisions were made.

An intraoperative diagnostic evaluation (e.g. flowmeter, Duplex scan, angiography, or combination of them) was performed on the basis of surgeon's or center's discretion to investigate graft patency and to identify any technical defects .

During all follow-up Duplex scans the diameter of the "arterialized" great saphenous vein was measured focusing on identifying residual fistulas, and intra-graft or anastomotic stenoses.

**Outcome measures**

All data related to the procedure were prospectively collected in a dedicated database. This included demographics, preoperative risk factors, clinical and diagnostic preoperative assessments, intraoperative features, and 30-day follow-up data.

The analysis of the cohort study was retrospectively performed.

Run-off status was determined depending on the amount of patent tibial vessels. If all tibial vessels were occluded the run-off was considered 0 and the distal anastomosis was performed on one of the foot arteries. A poor run-off status was considered in patients with 0-1 patent tibial vessels.

Intraoperative technical success was defined as obtaining a pulsatile vein in the in situ configuration without a conversion to another technique (e.g. reversed, spliced, or prosthetic graft).

Follow-up assessment included graft occlusion and major amputations.

A failing graft was defined as a patent vein graft however hemodynamically failing due to stenotic or occlusive lesions in the inflow or outflow arteries, anastomotic sites, or within the vein graft itself, increasing the risk of graft occlusion.

**Statistical analysis**

Estimated 2-year outcomes were evaluated in terms of primary patency, primary assisted patency, secondary patency, and limb salvage by life-table analysis (Kaplan-Meier test). Estimates were given with the 95% confidence intervals (CI).

Continuous data were expressed as the mean ± standard deviation (SD) or median with interquartile range (IQR) values when necessary. Categoric data were expressed as percentages. The nonparametric Pearson chi-square test was used when necessary to compare variables.

Uni- and multivariate analyses of the pre- or intra-operative factors affecting the primary patency, primary assisted patency, secondary patency, and limb salvage were performed by means of log-rank test and Cox regression analysis. Results of the regression analyses were presented as the hazard ratio (HR) and 95% CI.

Statistical significance was defined at the $p < .05$ level.

Statistical analysis was performed using SPSS software (version 24.0 for Apple; IBM Corporation, Armonk, NY, USA).

**RESULTS**

**Demographic and morphological data**

Patients were predominantly male (416, 76.9%) with a mean age of 73.1 ± 9.1 years (Table I).

The femoro-popliteal lesion was classified as “de novo” in 395 cases (73%), post-endovascular treatment in 140 cases (25.9%), and post-prosthetic bypass in 6 cases (1.1%).

The proportion of patients operated basing on Duplex results only was 159/541 cases (29.4%).

The mean occlusive lesion length was 37.8 ± 11.5 cm. In 170 cases (31.4%), the occlusive lesion was longer than 40 cm.

The median number of tibial run-off vessels was 2 (IQR 1-2). A poor run-off status (0-1 patent tibial arteries) was present in 240 patients (44.4%).

The mean diameter of the great saphenous vein was 4 ± 1.1 mm in the proximal part of the thigh, 3.7 ± 0.9 mm in the distal part of the thigh, 3.2 mm ± 0.8 mm in the proximal part of the leg, and 2.9 ± 0.7 mm in the distal part of the leg.

The great saphenous vein had a suprafascial tributary collateral and it was used for the distal anastomosis in 36 cases (6.7%).

According to the preoperative evaluation of the maximum diameter of the great saphenous vein, 72 patients (13.3%) were classified as *group 1.6-2.9 mm*, and the remaining 469 patients (86.7%) as *group ≥ 3 mm*.

More patients in *group 1.6-2.9 mm* had a suprafascial tributary collateral (87.7% vs. 72.2%; *p* = .014).

**Intraprocedural outcomes**

Intraoperative technical data and diagnostic assessment are reported in Table II.

The mean in situ saphenous bypass length was 49.3 ± 10.1 cm. In 194 cases (35.9%) the vein bypass was longer than 50 cm. Intraoperatively, a vasoactive drug (iloprost or nitrates) was used in 133 cases (24.6%). Based on preoperative mapping, incisions were performed ensuring ligation of the tributary veins of the great saphenous vein in all cases. In addition, intraoperative diagnostic evaluation was performed in 484 cases (89.5%).

The location of the proximal anastomosis was deep or superficial femoral artery in 172 cases (31.8%). A tibial artery was chosen as the site of the distal anastomosis in 184 patients (34%), and a foot artery was used in 22 cases (4.1%).

In all cases, technical success was obtained with a good pulsatility of the saphenous vein after the treatment with the valvulotome. The proximal anastomosis could be reached with the valvulotome in all cases. In 68 patients (12.6%), 4 or 5 valvulotome passes were needed.

Saphenous vein injury occurred in 19 cases (3.5%). In 12 cases (2.2%) an intramural haemorrhage or a small hole with active bleeding occurred; all cases were resolved without additional treatment. Five cases (0.9%) required replacement of the injured saphenous vein segment with autologous vein material (patch or tube graft). Furthermore, two cases (0.4%) required an endophlebectomy to remove a retained flow-limiting valve.

Vein injuries occurred in 17 patients of *group ≥ 3 mm* (3.6%) and in 2 patients of *group 1.6-2.9 mm* (2.8%). There was no statistically significant difference between the subgroups of patients ($p = .53$).

**Follow-up at 30-days**

The mean hospital stay was 11.1 ± 8.9 days and at discharge, the rate of overall bypass patency was 98.7%.

Postoperative medical therapy consisted in single antiplatelet therapy in 305 cases (56.3%), dual antiplatelet therapy in 115 cases (21.3%), and dual pathway inhibition in 121 cases (22.4%).

At 30-day follow-up, the overall mortality and major amputation rates were 3% and 0.9%, respectively.

Furthermore, 113 patients (20.9%) underwent a surgical reintervention within 30 days from the index procedure (Table III).

**Follow-up outcomes**

Follow-up was available in 506 patients (93.5%), with a mean follow-up period of 12.1 ± 7.5 months. Estimated 2-year overall survival was 84.9% (95% CI 81.7% to 87.2%).

During the follow-up examinations the mean maximum diameter of the great saphenous vein was 5.2 ± 1.6 mm with a positive mean increase (Δ) of 1.2 mm.

During the 1 to 24-month follow-up period, 50 graft occlusions were detected. Forty-four (88%) of them occurred within 1 year from the index procedure. In addition, limb preservation was not possible in 23 cases. In 22 patients major amputation occurred within 1 year from the index procedure.

The 2-year Kaplan-Meier estimates of primary patency, primary assisted patency, secondary patency, and limb salvage were 69.1% (95% CI 63.4% to 73.1%), 81.4% (95% CI 76.7% to 84.1%), 86.5% (95% CI 83.2% to 88.8%), and 94.5% (95% CI 92.3% to 96.6%), respectively (Fig. 1).

*Univariate analysis*

Table IV shows the univariate analysis at 2 years.

Primary patency was affected by history of coronary artery disease ($p = .033$), presence of a suprafascial tributary collateral ($p = .002$), preoperative vein diameter < 3 mm ($p < .001$), and distal anastomosis on a tibial/foot artery ($p = .022$).

Primary assisted patency was associated with the presence of a suprafascial tributary collateral ($p = .012$), preoperative vein diameter < 3 mm ($p < .001$), and distal anastomosis on a tibial/foot artery ($p = .014$).

Variables related to secondary patency included a history of coronary artery disease ($p = .010$), poor run-off status ($p = .023$), preoperative saphenous vein diameter < 3 mm ($p = .001$), and distal anastomosis on a tibial/foot vessel ($p = .014$).

Finally, limb salvage was affected by poor run-off status ($p$ = .008), presence of a suprafascial tributary collateral ($p$ = .009), preoperative saphenous vein diameter < 3 mm ($p$ = .008), and distal anastomosis on a tibial/foot artery ($p$ = .006).

*Multivariate analysis*

Multivariate analysis of the preoperative saphenous vein diameter < 3 mm confirmed the association with lower primary patency (HR 14.3, 95% CI 9.2 to 17.8, $p$ < .001), primary assisted patency (HR 9.4, 95% CI 7.9 to 11.3, $p$ = .002), secondary patency (HR 7.2, 95% CI 4.7 to 9.3, $p$ = .007), and limb salvage (HR 7.8, 95% CI 5 to 9.4, $p$ = .005) rates.

In addition, an association of distal anastomosis on a tibial/foot artery was confirmed with lower primary patency (HR 4.8, 95% CI 3.6 to 6.2, $p$ = .033), and primary assisted patency (HR 6, 95% CI 4.2 to 7.6, $p$ = .011) rates.

Finally, the presence of a suprafascial tributary collateral confirmed the association with lower primary patency (HR 6.7, 95% CI 4.6 to 8.2, $p$ = .013), and primary assisted patency (HR 4.2, 95% CI 3.2 to 5.4, $p$ = .042) rates.

## DISCUSSION

Open surgery is the preferred treatment for CLTI patients with long infrainguinal occlusions[1,2,16,17]. The great saphenous vein is the ideal conduit for surgical bypass in the lower limbs[2-4]. Alternative (small saphenous or arm) veins are acceptable bypass grafts even in spliced configuration, albeit an inferior durability to single-segment great saphenous conduits[18,19].

Over the last decades different vein bypass techniques have been proposed (reversed, in situ, ex situ, spliced, bifurcated); however, there is no evidence to support a preferred configuration for vein bypass grafting[2,20-23].

Calligaro et al.[7] firstly reported in 1991 no differences in terms of primary patency between in situ and reversed vein grafts. In the same year Bergmark et al.[8] demonstrated a better 6-month primary patency for in situ vein bypasses (84% vs. 49%). Later, Watelet et al.[11] published the 10-year outcomes of a randomized prospective study reporting a primary patency in favour of reversed grafts (64.5% vs. 41.7%). However, this difference was not found in veins larger than 4 mm.

Consequently, there was a need to create a national registry (LIMBSAVE) to prospectively collect contemporary data of CLTI patients undergoing in situ saphenous bypass. Preliminary outcomes of this registry have been published[24].

The majority of enrolled patients in the LIMBSAVE registry have TASC II D[25,26] with highly complex infrainguinal occlusions with a mean length of 40 cm and therefore, most often not amenable for endovascular treatment.

In the past, using older devices, Sasajima et al.[27] reported that an in situ vein bypass was not possible in 17.8% of the procedures.

However, using a new, innovative, hydrophilic valvulotome[14], the proximal anastomosis was reached and saphenous vein pulsatility was obtained in all patients enrolled into the LIMBSAVE registry.

In the present study, the rate of intraoperative vein injuries was low (3.5%), with a need for saphenous vein replacement in less than 1%. Additionally, in 0.4% of the cases an endophlebectomy was necessary to remove a retained flow-limiting valve. Shah et al.[6] reported that 31 retained valves (1.5%) have been excised during the follow-up. Nevertheless, the LIMBSAVE registry shows that intraoperative vein injury was not predictive for bypass occlusion and/or limb loss at 2 years.

The high rate of morbidity and mortality after peripheral vascular surgery is well known. Nowygrod et al.[28] reported that the rate of mortality after open peripheral surgery ranged from

3 to 4% in the period between 1998-2003. Shah et al.[6] further reported an early mortality rate of 3.7%. In our more elderly and diseased population the 30-day mortality rate was 3%.

The present study showed a reoperation rate (either open surgery, endovascular surgery, or hybrid surgery) for failed bypass of 5.9%. This is similar to the study of Shah et al.[6], which reports a reoperation rate of 5.9% for patients receiving a in situ saphenous vein for CLTI and is the biggest single-center experience reported in the literature (2058 patients).

Results showed no greater rate of perioperative complications in smaller veins. In fact, the blades of the valvulotome allowed to destroy the valves in the great saphenous veins with a diameter ranging from 1.5 to 6 mm.

However, the 2-year outcomes of overall patency and limb salvage in smaller veins were poorer than those obtained in veins with a preoperative diameter larger than 3 mm. Saphenous vein diameter has been considered a great limitation for the in situ technique. Shah et al.[6] reported no differences in terms of primary patency at 10 year follow-up between larger and smaller veins, although the "small" vein threshold was considered 4 mm. Watelet et al.[11] however, reported that the 10-year secondary patency was 37.5% for bypasses using veins with a diameter of $\leq 4$ mm and 80.6% for bypasses using veins $> 4$ mm ($p < .050$).

In addition, the multivariate analysis confirmed that anastomosis on a tibial/foot artery is a negative predictor of patency at 2 years. This is in line with other reports[29,30], which demonstrated that site of distal anastomosis is a key factor for the maintenance of the patency over the years.

Another factor affecting estimated 2-year patency was the use of a suprafascial tributary collateral as a graft. There is limited data available on the use of suprafascial tributary collaterals for the in situ saphenous vein bypass. The LIMBSAVE registry showed, however, that the suprafascial tributary collateral was associated with a smaller graft diameter. There

might be a correlation between poorer outcomes due to smaller saphenous veins and the use of suprafascial tributary collaterals. This however, needs further investigation.

Regardless of the diseased population included into the present registry, none of the preoperative examined demographic data demonstrated a strict correlation with poorer outcomes at 2-years. Even a poor run-off status did not affect overall patency and limb salvage rates at 2 years.

Several authors[31,32] have also demonstrated the importance of establishing an accurate surveillance protocol for patients undergoing peripheral vein grafts to perform graft preserving reinterventions whenever necessary before the vein graft becomes totally occluded.

The aim of such a high-grade surveillance protocol is to perform surgical reinterventions on the vein bypass to avoid graft failure[33,34]. In the present study the difference at 2 years between primary and primary assisted patency (69.1% vs. 81.4%) could be explained with an aggressive "endovascular" management to treat stenotic lesions at the anastomosis to improve the inflow and outflow of the vein graft.

Ultimately, this study has some limitations. Firstly, the registry is based on the concept of "real world". Thus, preoperative imaging varied significantly between centers well as postoperative antithrombotic medication. Secondly, the cohort study was retrospectively analyzed and there was no control group. So, there is no comparative data and the outcomes reported are related to a single group of patients treated with a standardized technique.

In conclusion, the LIMBSAVE registry showed an intraoperative technical success rate of 100% when using the HYDRO LeMaitre® Valvulotome for the in situ saphenous vein graft technique in patients with CLTI.

Our multicenter study on the use of infrainguinal in situ vein grafts in patients with CLTI demonstrated satisfactory outcomes in terms of patency of bypasses and limb saving. Duplex

ultrasound surveillance and targeted secondary interventions for developing vein graft stenosis are mandatory.

No patient variables affected the 2-year outcomes, whereas the preoperative saphenous vein diameter < 3 mm, distal anastomosis on a tibial/foot artery, and use of suprafascial tributary collateral as a graft affected estimated 2-year overall patency and limb salvage rates. Further examinations and continuous follow-up are needed to evaluate the long-term outcomes.

## AUTHORS' CONTRIBUTIONS

**Nicola Troisi,** writing, data analysis, data interpretation, final revision, final approval

**Daniele Adami,** data interpretation, final revision, final approval

**Stefano Michelagnoli,** data analysis, final revision, final approval

**Raffaella Berchiolli,** data analysis, final revision, final approval

**LIMBSAVE registry Collaborative Group**, data collection

All authors read and approved the final version of the manuscript.

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**Conflict of interest statement**

Declarations of interest: none.

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Tab. I. Demographic data and preoperative risk factors.

| **Demographics** | |
|---|---|
| Males | 416 (76.9%) |
| Age, y | 73.1 |
| >80 years | 142 (26.2%) |
| Risk factors | |
| Smoking | 192 (35.5%) |
| Former smoking | 187 (43.7%) |
| Hypertension | 475 (87.8%) |
| Hypercholesterolemia | 308 (56.9%) |
| Diabetes mellitus | 258 (47.7%) |
| Insulin treatment | 148 (27.4%) |
| Coronary artery disease | 220 (40.7%) |
| Chronic renal failure* | 123 (22.7%) |
| Dialysis treatment | 41 (7.6%) |
| Previous deep venous thrombosis | 4 (0.7%) |
| Rutherford classification | |
| 4 (rest pain) | 176 (32.5%) |
| 5 (minor tissue loss) | 234 (43.3%) |
| 6 (major tissue loss) | 131 (24.2%) |

Continuous data are presented as the means; categorical data are given as the counts (percentage).
*Glomerular filtration rate <30 mL/min.

Tab. II. Intraprocedural data including sites of anastomosis.

| **Technical data** | |
|---|---|
| Anaesthesia | |
| General | 337 (62.3%) |
| Locoregional | 167 (30.9%) |
| Peripheral nerve block | 37 (6.8%) |
| Proximal anastomosis | |
| Common femoral artery | 369 (68.2%) |
| Superficial femoral artery | 147 (27.1%) |
| Deep femoral artery | 9 (1.7%) |
| Popliteal artery | 16 (3%) |
| Distal anastomosis | |
| Popliteal artery | 335 (61.9%) |
| Tibioperoneal trunk | 67 (12.4%) |
| Posterior tibial artery | 56 (10.4%) |
| Peroneal artery | 32 (5.9%) |
| Anterior tibial artery | 29 (5.4%) |
| Foot artery | 22 (4.1%) |
| **Completion imaging** | |
| Nothing | 57 (10.5%) |
| Duplex scan | 268 (49.5%) |
| Duplex scan + flowmeter | 22 (4.1%) |
| Duplex scan + angiography | 26 (4.8%) |
| Angiography | 99 (18.3%) |
| Angiography + flowmeter | 3 (0.6%) |
| Flowmeter | 57 (10.5%) |
| CW-Doppler | 9 (1.7%) |

categorical data are given as the counts (percentage).

Tab. III. Early results (< 30 days) including all-cause morbidity, and reoperation for thrombosed/failing bypass.

| | **n. patients (%)** |
|---|---|
| **Overall mortality** | 16 (3%)<br>- 7 (43.6%) acute myocardial infarction<br>- 1 (6.3%) acute heart failure<br>- 2 (12.5%) sepsis<br>- 1 (6.3%) MOF<br>- 1 (6.3%) pulmonary embolism<br>- 1 (6.3%) pneumonia<br>- 3 (18.7%) unknown |
| **Systemic morbidity** | 36 (6.7%)<br>- 17 (47.2%) acute myocardial infarction<br>- 7 (19.3%) acute heart failure<br>- 4 (11.1%) sepsis<br>- 2 (5.6%) pneumonia<br>- 2 (5.6%) acute renal failure<br>- 1 (2.8%) deep venous thrombosis<br>- 1 (2.8%) MOF<br>- 1 (2.8%) pulmonary embolism<br>- 1 (2.8%) pneumonia |
| **Reoperation for thrombosed or failing bypass** | 32 (5.9%)<br>- 16 (50%) open<br>- 11 (34.3%) endovascular<br>- 5 (15.7%) hybrid |
| **Other surgical procedures** | 81 (15%)<br>- 5 (6.2%) major amputation<br>- 34 (42%) minor amputation<br>- 8 (9.9%) ligation of patent tributaries<br>- 5 (6.2%) bleeding<br>- 26 (32.1%) surgical site dehiscence<br>- 2 (2.4%) lymphocele<br>- 1 (1.2%) surgical site infection |

MOF, multi organ failure

Tab. IV. Univariate analysis of factors affecting primary patency, primary assisted patency, secondary patency, and limb salvage rates at 2 years.

| | Primary patency (%) | *p* | Primary assisted patency (%) | *p* | Secondary patency (%) | *p* | Limb salvage (%) | *p* |
|---|---|---|---|---|---|---|---|---|
| **Sex** | | | | | | | | |
| - male | 67.7% | .43 | 79.8% | .25 | 86% | .72 | 94.7% | .53 |
| - female | 73.1% | | 86% | | 87.6% | | 93.6% | |
| **Age** | | | | | | | | |
| - <80 years | 69.4% | .48 | 80.2% | .062 | 86.5% | .53 | 94.4% | .92 |
| - >80 years | 67.4% | | 84.5% | | 86% | | 95% | |
| **Active smoking** | | | | | | | | |
| - yes | 70.5% | .47 | 80.3% | .33 | 84.2% | .31 | 93.2% | .31 |
| - no | 67% | | 84.3% | | 89.4% | | 96.2% | |
| **Hypertension** | | | | | | | | |
| - yes | 70.1% | .63 | 80.2% | .12 | 85.6% | .32 | 94.3% | .84 |
| - no | 65% | | 89.8% | | 91.6% | | 94.5% | |
| **Hypercholesterolemia** | | | | | | | | |
| - yes | 68.3% | .37 | 78.1% | .23 | 83.6% | .14 | 93% | .22 |
| - no | 70.3% | | 85.9% | | 90.3% | | 96.6% | |
| **Diabetes mellitus** | | | | | | | | |
| - yes | 70.1% | .78 | 81.2% | .31 | 87.4% | .82 | 92.5% | .21 |
| - no | 68.5% | | 81.9% | | 85.8% | | 96.2% | |
| **Insulin treatment** | | | | | | | | |
| - yes | 70.9% | .87 | 81.7% | .33 | 87.1% | .28 | 92.8% | .2 |
| - no | 68.6% | | 81.4% | | 86.4% | | 95.2% | |
| **Coronary artery disease** | | | | | | | | |
| - yes | 65.6% | **.033** | 76.7% | .08 | 80.6% | **.010** | 94% | .33 |
| - no | 71.6% | | 84.3% | | 89.9% | | 94.9% | |
| **Chronic renal failure** | | | | | | | | |
| - yes | 73.3% | .12 | 83.9% | .63 | 86.3% | .89 | 94.5% | .57 |
| - no | 68.1% | | 80.7% | | 86.9% | | 94.5% | |
| **Dialysis treatment** | | | | | | | | |
| - yes | 86.9% | .064 | 92.9% | .12 | 95.8% | .11 | 97.4% | .61 |
| - no | 67.8% | | 80.6% | | 85.8% | | 94.3% | |
| **Rutherford category** | | | | | | | | |
| - 4 | 70% | .91 | 80.1% | .54 | 86.5% | .86 | 95.5% | .24 |
| - 5-6 | 70.5% | | 82.1% | | 86.5% | | 94% | |
| **Lesion** | | | | | | | | |
| - de novo | 69.2% | .52 | 82% | .43 | 86.3% | .43 | 94.8% | .83 |
| - post endo/surgery | 67.6% | | 81.2% | | 86.7% | | 93.5% | |
| **Lesion length > 40 cm** | | | | | | | | |
| - yes | 66.8% | .073 | 81.6% | .92 | 85.8% | .92 | 95.8% | .64 |
| - no | 70.4% | | 80.2% | | 86.5% | | 94.1% | |
| **Run-off tibial vessels** | | | | | | | | |
| - 0-1 | 69.8% | .20 | 81% | .13 | 84.9% | **.023** | 92.1% | **.008** |
| - 2-3 | 68.6% | | 82% | | 87.9% | | 96.4% | |
| **Great saphenous vein** | | | | | | | | |
| - Suprafascial tributary collateral | 46.7% | **.002** | 68.1% | **.012** | 81.4% | .23 | 84.2% | **.009** |
| - Intrafascial | 70.6% | | 82.2% | | 86.7% | | 95.1% | |
| **Vein diameter** | | | | | | | | |
| - 1.6-2.9 mm | 43.9% | **< .001** | 63.4% | **< .001** | 72.5% | **.001** | 88% | **.008** |
| - ≥ 3 mm | 73% | | 84.1% | | 88.5% | | 95.4% | |
| **Proximal anastomosis** | | | | | | | | |
| - Common femoral artery | 70.7% | .83 | 83.9% | .71 | 85.6% | .85 | 94.6% | .48 |
| - Other | 68.1% | | 79.9% | | 87.6% | | 94.2% | |
| **Distal anastomosis** | | | | | | | | |
| - Popliteal artery | 71% | **.022** | 83.8% | **.014** | 87.9% | **.014** | 96.4% | **.006** |
| - Tibial/foot vessel | 66% | | 77.4% | | 84% | | 91.4% | |
| **Bypass length > 50 cm** | | .11 | | .63 | | .31 | | .62 |

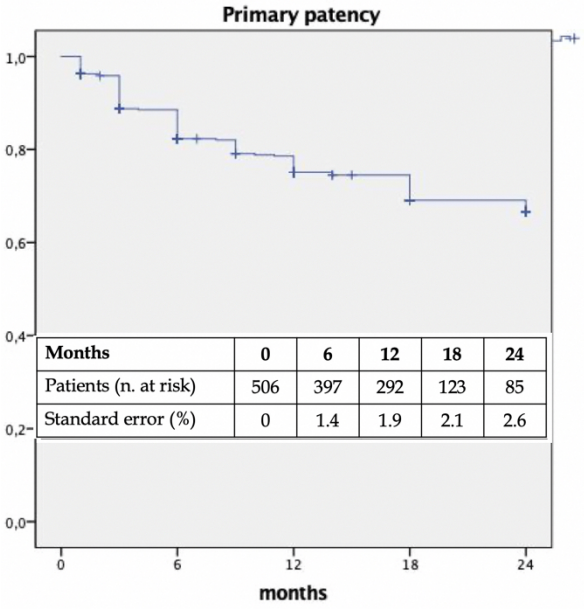
| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| - yes | 67.5% | | 80.9% | | 89.2% | | 94.5% | |
| - no | 70.1% | | 82.6% | | 85.3% | | 94.6% | |
| **Intraoperative vein lesion** | | | | | | | | |
| - yes | 72.6% | .52 | 81.3% | .72 | 84.7% | .83 | 94.1% | .67 |
| - no | 69.1% | | 84.7% | | 86.5% | | 94.5% | |

1

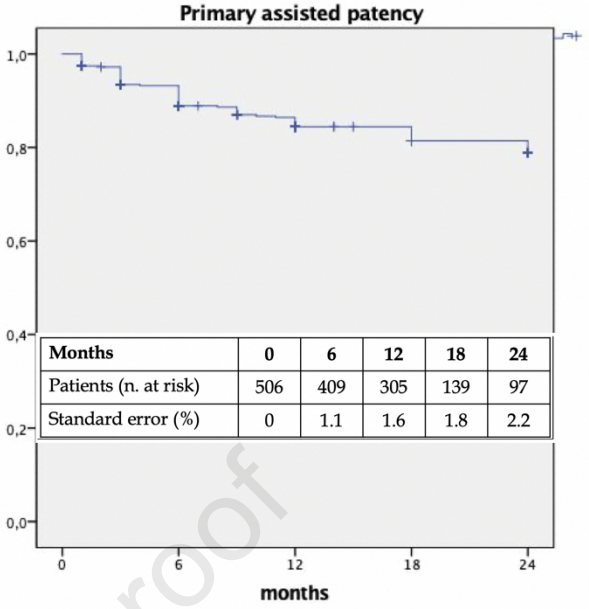
2

**FIGURE LEGENDS**

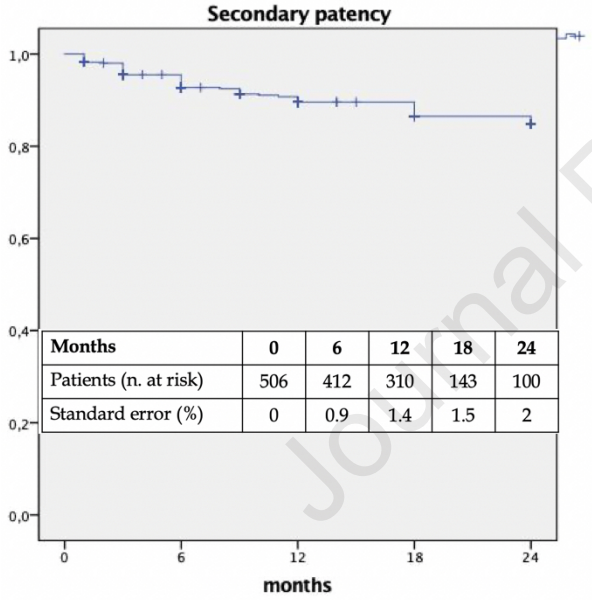
Fig. 1. Estimated 2-year primary patency, primary assisted patency, secondary patency, and limb salvage (Kaplan-Meyer curves with number of patients at risk and standard error values for each group).



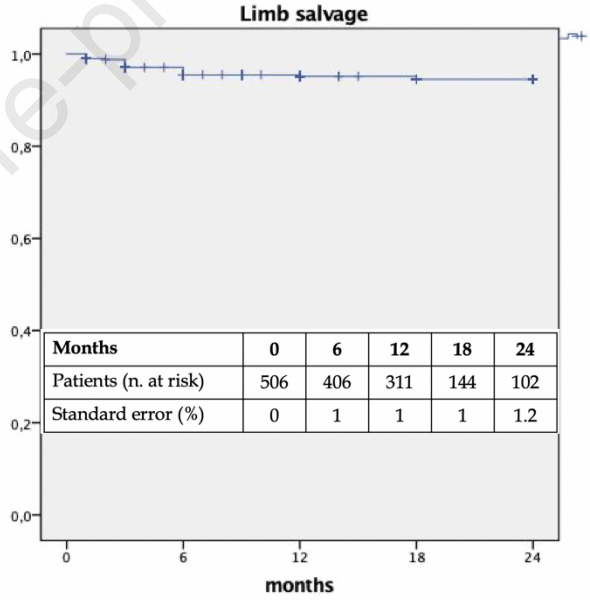

| Months | 0 | 6 | 12 | 18 | 24 |
|---|---|---|---|---|---|
| Patients (n. at risk) | 506 | 397 | 292 | 123 | 85 |
| Standard error (%) | 0 | 1.4 | 1.9 | 2.1 | 2.6 |




| Months | 0 | 6 | 12 | 18 | 24 |
|---|---|---|---|---|---|
| Patients (n. at risk) | 506 | 409 | 305 | 139 | 97 |
| Standard error (%) | 0 | 1.1 | 1.6 | 1.8 | 2.2 |




| Months | 0 | 6 | 12 | 18 | 24 |
|---|---|---|---|---|---|
| Patients (n. at risk) | 506 | 412 | 310 | 143 | 100 |
| Standard error (%) | 0 | 0.9 | 1.4 | 1.5 | 2 |




| Months | 0 | 6 | 12 | 18 | 24 |
|---|---|---|---|---|---|
| Patients (n. at risk) | 506 | 406 | 311 | 144 | 102 |
| Standard error (%) | 0 | 1 | 1 | 1 | 1.2 |